



May 29, 2025

Shanghai AnQing Medical Instrument Co., Ltd.  
Shuwen Fan  
RA Manager  
3 & 4 Floor, No.2 Building, 366 Huiqing Rd  
East Zhangjiang High-Tech Park  
Shanghai, 201201  
China

Re: K243497

Trade/Device Name: Portable Video Processor (EA101), Flexible Bronchoscope (BS41H-12EU, BS41H-12US, BS46H-17EU, BS50H-20EU, BS46H-17US, BS50H-20US, BS53H-22EU, BS53H-22US, BS55H-24EU, BS55H-24US, BS59H-28EU, BS59H-28US)

Regulation Number: 21 CFR 874.4680

Regulation Name: Bronchoscope (Flexible Or Rigid) And Accessories

Regulatory Class: Class II

Product Code: EOQ

Dated: April 28, 2025

Received: April 28, 2025

Dear Shuwen Fan:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of

Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the

Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Joyce C. Lin -S

for Shu-Chen Peng, Ph.D.

Assistant Director

DHT1B: Division of Dental and  
ENT Devices

OHT1: Office of Ophthalmic, Anesthesia,  
Respiratory, ENT, and Dental Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

## Indications for Use

Submission Number (if known)

K243497

Device Name

Portable Video Processor (EA101);  
Flexible Bronchoscope (BS41H-12EU, BS41H-12US, BS46H-17EU, BS46H-17US, BS50H-20EU,  
BS50H-20US, BS53H-22EU, BS53H-22US, BS55H-24EU, BS55H-24US, BS59H-28EU,  
BS59H-28US)

Indications for Use (Describe)

The Flexible Bronchoscopes have been designed to be used with the video processor, endotherapy accessories and other ancillary equipment for endoscopy within the airways and tracheobronchial tree.

The Bronchoscope System is for use in a hospital environment. The Flexible Bronchoscope is a single-use device designed for use in adults.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
[PRASuff@fda.hhs.gov](mailto:PRASuff@fda.hhs.gov)

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

## Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

Applicant Name	Shanghai AnQing Medical Instrument Co., Ltd.
Applicant Address	3 & 4 Floor, No.2 Building, 366 Huiqing Rd, East Zhangjiang High-Tech Park Shanghai 201201 China
Applicant Contact Telephone	+86-21-61117375
Applicant Contact	Ms. Shuwen Fan
Applicant Contact Email	ra_dept@anqing-sh.com

## Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	Portable Video Processor (EA101); Flexible Bronchoscope (BS41H-12EU, BS41H-12US, BS46H-17EU, BS46H-17US, BS50H-20EU, BS50H-20US, BS53H-22EU, BS53H-22US, BS55H-24EU, BS55H-24US, BS59H-28EU, BS59H-28US)
Common Name	Bronchoscope (flexible or rigid) and accessories
Classification Name	Bronchoscope (Flexible Or Rigid)
Regulation Number	874.4680
Product Code(s)	EOQ

## Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K211169	Bronchoscope System	EOQ

## Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

The Bronchoscope System comprises two components: (1) a Portable Video Processor (model: EA101) and (2) a compatible Flexible Bronchoscope (model: BS41H-12EU, BS41H-12US, BS46H-17EU, BS46H-17US, BS50H-20EU, BS50H-20US, BS53H-22EU, BS53H-22US, BS55H-24EU, BS55H-24US, BS59H-28EU, BS59H-28US).

The Flexible Bronchoscopes are the same devices as cleared in K211169, except the following changes:

1. The bronchoscopes are now also compatible to Portable Video Processor.
2. Package configuration change.

The Flexible Bronchoscope is inserted through the airways and tracheobronchial tree during bronchoscopy. The Video Processor provides power and processes the images for medical electronic endoscope. The Portable Video Processor consists a 13.3" LCD touch screen. It is powered through a Lithium-ion battery or a separate power adaptor.

The Flexible Bronchoscope has following physical and performance characteristics:

- Maneuverable tip controlled by the user
- Flexible insertion cord
- CMOS Camera and LED light source at the distal tip
- Sterilized by Ethylene Oxide
- For single use

Portable Video Processor has following physical and performance characteristics:

- Displays the image from the Flexible Bronchoscope on the built-in screen.
- Can be connected to an external monitor.
- Non-sterile Reusable device.

Mechanism of action:

The light emitted by the LED cold light source at the distal tip of the endoscope is irradiated into the body cavity, and the light reflected from the cavity enters the optical system and is captured by the CMOS image sensor. The CMOS acquisition image is controlled by the CMOS drive circuit, and the RGB video signal is output to the Portable Video Processor. The Portable Video Processor receives video signals from the endoscope, processes the video signals, and outputs the processed video signal to the built in monitor or attached external monitor. The video processor also controls the brightness of the LEDs on the endoscope.

## Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

The Flexible Bronchoscopes have been designed to be used with the video processor, endotherapy accessories and other ancillary equipment for endoscopy within the airways and tracheobronchial tree.

The Bronchoscope System is for use in a hospital environment. The Flexible Bronchoscope is a single-use device designed for use in adults.

## Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

The indications for use are the same.

## Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

The Bronchoscope System comprises two components: (1) a Portable Video Processor and (2) a compatible Flexible Bronchoscope.

The subject Flexible Bronchoscopes are the same device as cleared in K211169, except the following changes:

1. The bronchoscopes are now also compatible to Portable Video Processor.
2. Package configuration.

The subject device Portable Video Processor (EA101) and its predicate device, the Video Processor (EOS-H-01), have the following same technological characteristics:

- Both are displaying live video-imaging data of the connected endoscope to a monitor
- Both provide video output formats, recording and data storage functions.
- Both share certain technical functionality such as brightness control, image scaling up/down, white balance manually.

The differences between the subject device Portable Video Processor (EA101) and the predicate device are as follows:

- Portable Video Processor can be hung on an IV pole by means of a bracket.
- Portable Video Processor has a built-in LCD screen that provides live imaging data in addition to the possibility to connect to an external monitor.
- Portable Video Processor can be powered through a Lithium-ion battery.
- Portable Video Processor does not have USB port. There is no data exchange functions available for the subject device.

## Non-Clinical and/or Clinical Tests Summary & Conclusions

[21 CFR 807.92\(b\)](#)

### 1. Electrical Safety and Electromagnetic Compatibility Summary

The electrical safety and EMC data included in the submission is in compliance with the following FDA recognized standards:

- ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]
- ANSI AAMI IEC 60601-1-2:2014 [Including AMD 1:2021]
- IEC 60601-2-18 Edition 3.0 2009-08
- IEC/TR 60601-4-2 Edition 1.0 2016-05

### 2. Photobiological safety

The proposed device was tested according to the following FDA recognized standards:

- IEC 62471:2006 Medical electrical equipment, Photobiological safety of lamps and lamp systems

### 3. Optical Performance

The proposed device was designed to comply with applicable parts of ISO 8600. Optical measurements were performed according to applicable part of ISO 8600 standard.

In addition, comparative testing related to image quality parameters including direction of view, field of view, MTF/DOF, color performance, SNR/Dynamic Range, Distortion, and Image intensity uniformity was performed for proposed device and the predicate device to support substantial equivalence.

Other performance data of the Flexible Bronchoscope cleared via K211169 is applicable.

4. The biocompatibility evaluation for the patient contacting components of the proposed device was performed according to ISO 10993-1 and FDA Guidance. The following tests were conducted: Cytotoxicity, Sensitization, Irritation, Material-mediated pyrogenicity, Acute systemic toxicity.

#### 5. Sterilization and shelf life testing

The sterilization method has been validated to ISO 11135:2014, which has thereby determined the routine control and monitoring parameters.

EO/ECH residual test was performed according to ISO 10993-7:2008.

The shelf life of the proposed device is determined based on stability study which includes aging test according to ASTM F1980-21, Standard Guide for Accelerated Aging of Sterile Barrier.

#### 6. Package Validation

Package validation was conducted according to ISO 11607-1:2019 and ISO 11607-2:2019, and ASTM F88/F88M-21, ASTM F1929-15. Transport and shipping testing as per ASTM D4169-22.

#### 7. Software

Software verification and validation were conducted according to IEC 62304: 2006 + A1: 2015 and FDA Guidance for Industry and Staff "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".

Not Applicable.

The conclusions drawn from the nonclinical tests demonstrate that the subject device, the Flexible Bronchoscope System is as safe, as effective, and performs as well as the legally marketed device identified above.